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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,176	03/31/2004	Paul A. Negulescu	AUOBIO.036A	7072

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EXAMINER

PAGANS, AMANDA J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/815,176	NEGULESCU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amanda J. Pagans	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

*RP*

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a multiwell plate assembly comprising a first tray of sample wells and a second tray of sample wells coupled to form a plurality of assay chambers, each chamber having a first compartment, a second compartment, and at least one cell layer separating the two chambers, classified in class 435, subclass 288.4, for example.
- II. Claims 18-20, drawn to a testing process for characterizing the biological activity of a compound, classified in class 435, subclass 4, for example.
- III. Claims 21-27, drawn to a single multiwell plate apparatus immersed in a gel, classified in class 435, subclass 288.5, for example.
- IV. Claims 28-32, drawn to a pair of multiwell plates forming multiple dual-compartment wells, the wells of the second plate being sloped, classified in class 435, subclass 287.8, for example.
- V. Claims 33-36, drawn to a pair of multiwell plates positioned to form dual-compartment wells, with a pair of circuit boards sandwiching the plates, classified in class 435, subclass 287.1, for example.
- VI. Claims 37-38, drawn to a multi-channel voltage clamp, classified in class 435, subclass 287.1, for example.

- VII. Claim 39, drawn to an assay apparatus comprising an array of dual-compartment assays, corresponding array of electrodes, and multi-channel electronic control and sensing circuitry, classified in class 435, subclass 287.1, for example.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Invention I as claimed can be used for testing the effect of changes in temperature or radiation, for example, have on the electrical properties of cells.

Inventions I and III through VII are distinct from each other, as evidenced by the claims themselves- i.e., a multiwell plate assembly comprising two trays coupled together to form multiple assay chambers made up of two compartments separated by at least one cell layer and having an electrode passing through the wall of the first compartment (Invention I), a single multiwell plate containing electrodes immersed in a gel, a circuit board, and terminal blocks, with each well having a top opening, a bottom panel (Invention III), an apparatus comprising electrodes, a pair of multiwell plates aligned one on top of the other, and the wells of one of the multi-well plates having sloped surfaces (Invention IV), a pair of adjacent multiwell plates forming multiple dual-compartment wells, a pair of printed circuit boards with electrodes extending from each, sandwiching the pair of multiwell plates, and having digitally controlled amplifier

Art Unit: 1651

electronics coupled to the electrodes (Invention V), a multi-channel voltage clamp comprising voltage sensors coupled to dual-compartment assays, a digitally programmable controller, and servo amplifiers (Invention VI), and an apparatus of dual-compartment assays with corresponding electrodes in each compartment, and multi-channel digitally programmable electronic control and sensing circuitry (Invention VII).

The several inventions above are independent and distinct, each from the other. They acquired a separate status in the art and require independent searches. The search of each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would further anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

Art Unit: 1651

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda J. Pagans whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571)272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda J. Pagans  
Examiner  
USPTO

A handwritten signature in black ink, appearing to read 'CHRISTOPHER R. TATE', with a stylized, looping flourish at the end.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER